

REMARKS

By this Amendment, Claims 1, 3, 8, 10, 13, 15, 17-24, 28, 30, 31, and 36-39 are amended, and new Claims 40-42 are added. Accordingly, Claims 1-42 are pending.

Applicants propose to amend FIG. 3 of the drawings to add reference numbers 145 and 152 and associated lead lines to indicate the locations of the solenoid 145 and puncture element 152, respectively. Support for these amendments is provided at page 9, lines 16-19, of the specification.

The specification is amended to correct minor informalities.

A marked-up copy of the Abstract is attached on a separate sheet. The Abstract addresses the formalities raised in the Office Action.

Reconsideration of the February 11, 2003 Official Action is respectfully requested.

Initially, Applicants thank Examiner Weiss for the courtesies extended to Applicants' undersigned representative during the April 25, 2003 personal interview. Applicants' record of the substance of the interview is incorporated in the following remarks.

The Official Action states that the documents cited in the Information Disclosure Statement filed on March 20, 2002, have not been considered. However, as was discussed during the personal interview, copies of each of the cited documents were submitted to the Patent Office along with the Information Disclosure Statement. Examiner Weiss indicated that he will try to locate the copies when this response is acted on. Applicants request that they be provided with an initialed Form PTO-1449 acknowledging consideration of the documents along with the next Patent Office communication.

Applicants gratefully acknowledge the indication in the Official Action that Claim 8 contains allowable subject matter. Claim 8 is amended to include the combinations of features of Claims 1 and 8. Accordingly, Claim 8 is allowable.

Claims 1-39 stand rejected under 35 U.S.C. § 112, second paragraph. The reasons for the rejection are stated at pages 2-3 of the Official Action. The rejection is respectfully traversed for the following reasons.

Claims 1, 3, 10, 15, 18-22, 24, 31, and 36-39 are amended to change the term "fluid" to "liquid". Claims 1, 10, 15, 17, 21, 23, and 37 are amended to change the term "volatilized fluid" to "vapor". These amendments clarify that liquid is volatilized by heating to produce vapor. Support for the amendments is provided at page 11, lines 14-16, of the specification. Applicants submit that these amendments do not narrow the scope of Claims 1, 3, 10, 15, 17-24, 31, and 36-39, but rather make express subject matter that was implicit in these claims, as originally filed.

Claim 1 also is amended to recite "an outlet which can be opened to expel vapor". Support for this amendment is provided at page 8, lines 7-8, of the specification. Claims 10, 13, 15, 17, 19, 21, 23, 28, 30, and 37 are amended to be consistent with amended Claim 1. Applicants submit that these amendments do not narrow the scope of Claims 1, 10, 13, 15, 17, 19, 21, 23, 28, 30, and 37, but rather make express subject matter that was implicit in these claims, as originally filed.

Claims 13, 21 and 23 are amended to change the recitation of "the first and/or second layer" to "at least one of the first and second layer". Applicants submit that these

recitations have the same meaning in the context of the claimed aerosol generator, and thus the amendments do not narrow the scope of Claims 13, 21 and 23.

Applicants submit that the amendments fully address each of the assertions stated in the Official Action. Accordingly, withdrawal of the rejection is respectfully requested.

Claims 1, 5-7, 10-12, 17, 25, and 26 stand rejected under 35 U.S.C. § 102(b) over U.S. Patent No. 4,012,472 to Lindsey. The reasons for the rejection are stated at pages 4-6 of the Official Action. The rejection is respectfully traversed for the following reasons.

Claim 1, as amended, recites a disposable aerosol generator for use with an inhaler device including a heater adapted to volatilize liquid stored in the aerosol generator, the aerosol generator comprising *inter alia* "a disposable body including a sealed chamber and an outlet which can be opened to expel vapor, . . . the chamber accommodating a predetermined volume of a liquid which is expelled through the opened outlet as vapor when the liquid in the chamber is volatilized by the heater" (emphasis added). In the recited aerosol generator, liquid is provided in a sealed chamber. In order to generate an aerosol, the liquid is volatilized in the chamber by a heater and expelled through the opened outlet. Lindsey fails to disclose or suggest the combination of features recited in Claim 1.

The Official Action asserts that Lindsey discloses a disposable aerosol generator for use with an inhaler device, which includes a heater 147 adapted to volatilize fluid stored in the aerosol generator. The Official Action further asserts that Lindsey's disclosed aerosol generator comprises a disposable body (101/131) and an outlet 123, that the disposable body includes first and second layers of material defining the chamber, and that the chamber accommodates a predetermined volume of a fluid, which is expelled through the

outlet when the fluid in the chamber is volatilized by the heater. The Official Action asserts that Figs. 10 and 11 of Lindsey "show this intended result". Applicants respectfully disagree with these assertions for the following reasons.

Lindsey discloses a medical fluids container. Figures 1 and 2 of Lindsey show a nebulizer/humidifier apparatus for use with oxygen breathing systems. The apparatus includes a flexible bag 101, and a passageway 103 within the bag 101, which may be used to pass oxygen into the bag or to draw water out of the bag (column 3, lines 16-24). The apparatus also includes a hole 123, which the Official Action asserts is "an outlet", as recited in Claim 1. The hole 123 is formed before assembly (column 4, lines 14-16). The apparatus also includes a housing unit 107, which connects to the bag 101. As shown in Figure 6A of Lindsey, the housing unit 107 holds a water heater insert 147 (column 6, lines 29-33). As shown in Figure 8 of Lindsey, the heater insert 147 includes a heater element 209 and a tortuous canal 211.

Lindsey discloses that the apparatus can be operated in a nebulizer mode (see Figure 10) or a humidifier mode (see Figure 11). In the nebulizer mode, oxygen is fed to a nozzle from a water reservoir in the bag 101 via the passageway slits 127 disposed at one end of the bag 101, the passageway 103, the tortuous heater canal 211, where the water is heated, and other described passages. Oxygen is fed to the nozzle via the oxygen supply connector 109 and the second chamber 169. Lindsey discloses that a mixture of oxygen and water droplets is formed and passed into the bag 101. The mixture is mixed with room air (column 11, line 59 - column 12, line 27).

Lindsey fails to disclose or suggest that liquid is volatilized in the bag 101 by the heater insert, or that vapor is expelled through the hole 123. As explained above, the passageway 103 is used to draw water out of the bag 101. Lindsey does not disclose or suggest that water is volatilized by heating anywhere in the apparatus. In fact, Lindsey discloses that "the heater insert may be used with or without a heater element" (column 12, lines 51-52). This latter disclosure further confirms that heating of the liquid in the bag is not required during operation of the apparatus. Lindsey further does not disclose or suggest that vapor is expelled from the bag.

Lindsey also fails to disclose or suggest that liquid is volatilized in the bag 101 and expelled as vapor through the hole 123 in the humidifier mode (column 12, lines 28-42).

Accordingly, Lindsey fails to disclose or suggest the combination of features recited in Claim 1. Therefore, Claim 1 is patentable over Lindsey. Claims 2, 5-7, 10-12, 17, and 25-26 depend from Claim 1 and, accordingly, are also patentable over Lindsey for at least the same reasons as those for Claim 1. Withdrawal of the rejection is therefore respectfully requested.

Claims 3, 4, 9, 15, 18, 19, 20-24, 27-33, and 37-39 stand rejected under 35 U.S.C. § 103(a) over Lindsey. The reasons for the rejection are stated at pages 6-11 of the Official Action. The rejection is respectfully traversed for the following reasons.

As explained above, Lindsey fails to disclose or suggest the combination of features recited in Claim 1. Accordingly, Lindsey also fails to disclose or suggest the combinations of features recited in dependent Claims 3-4, 9, 15, 18-19, 20-24, 27-33, and 37-39 for at

least the same reasons as those for Claim 1. Thus, these dependent claims also are patentable over Lindsey. Therefore, withdrawal of the rejection is respectfully requested.

Claims 13, 14, 19, 28, 30, and 34-36 stand rejected under 35 U.S.C. § 103(a) over Lindsey in view of U.S. Patent No. 6,116,238 to Jackson. The reasons for the rejection are stated at page 11 of the Official Action. The rejection is respectfully traversed for the following reasons.

Claims 13, 14, 19, 28, 30, and 34-36 depend from Claim 1. The Official Action acknowledges that Lindsey fails to disclose the combination of features recited in these claims. However, Jackson fails to cure the deficiencies of Lindsey with respect to the combination of features recited in Claim 1. Particularly, Jackson fails to suggest an aerosol generator as recited in Claim 1. Accordingly, Jackson provides no motivation to modify Lindsey to achieve the subject matter recited in Claim 1. Accordingly, Claims 13, 14, 19, 28, 30, and 34-36 also are patentable over Lindsey and Jackson for at least the same reasons as those for Claim 1.

Claims 1-39 stand rejected under the doctrine of obviousness-type double patenting over Claims 1-28 of U.S. Patent Application Serial No. 09/742,321. The reasons for the rejection are stated at pages 12-13 of the Official Action.

Applicants have attached hereto a Terminal Disclaimer in compliance with 37 CFR § 3.73(b). The rejection is believed to be overcome, and Applicants therefore respectfully request its withdrawal.

New Claim 40 depends from Claim 1, and recites a Markush group of medicaments that can be included in the liquid. Support for the subject matter recited in Claim 40 is

provided at page 5, lines 11-18, of the specification. Claim 40 also is patentable for at least the same reasons as those for Claim 1.

New independent Claim 41 is directed to a disposable aerosol generator, which comprises *inter alia* "a disposable body including a sealed chamber and an outlet which can be opened to expel vapor, . . . the chamber being sized to accommodate a single dose of a liquid which is expelled through the opened outlet as vapor when the liquid in the chamber is volatilized by the heater" (emphasis added). Support for the subject matter recited in Claim 41 is provided at page 6, lines 18-19, of the specification. Applicants respectfully submit that the combination of features recited in Claim 41 also is patentable.

New Claim 42 depends from Claim 41 and recites the same features recited in Claim 40. Claim 42 also is patentable.

For the foregoing reasons, withdrawal of the rejections and prompt allowance of the application are respectfully requested.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By:



Edward A. Brown
Registration No. 35,033

P.O. Box 1404
Alexandria, Virginia 22313-1404
703-836-6620

Date: June 2, 2003